UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,299	08/20/2004	Jacob Waugh	4649-4007	3791

65989 7590 06/19/2007

KING & SPALDING
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-4003

EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,299	WAUGH ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2007 has been entered.

Claims 44-85 are pending in the application and are being examined on the merits herein.

Applicant's arguments regarding the rejections of the claims have been fully considered but they are not persuasive. The claims are rejected as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 44-69, 71, 76-77, 79 and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002.

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine (se paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular), and thus teaches providing a dermatologically acceptable vehicle.

Rothbard et al. does not teach a specific example of composition having a polymer comprising from 7 to 15 subunits of L-arginine in a cosmetically or dermatologically acceptable vehicle. However, as Rothbard et al. teaches that the transport enhancing polymers can comprise from 7 to 15 amidino moieties, such as

heptamers, octamers and nonamers of arginine, which may be L-arginines, and furthermore teaches that such transport enhancing agent can be formulated with pharmaceutical carriers for topical administration, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide a polymer having a number of arginine subunits within the range recited in claim 44, and with a dermatologically acceptable vehicle, with the expectation of providing a transport enhancing composition suitable for topical application.

Regarding the recitation that the composition comprises a "vasodilating amount of polymer," as recited in claims 44 and 56, it is noted that Rothbard et al. teaches the composition having the transport enhancer can generally comprise from about 5% to about 75% by weight of a compound/transport combination (see paragraph 0128.) An amount of 5% to 75% is believed be substantial enough range to provide overlap and/or to come close to an amount that would also have vasodilating properties. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the transport enhancer provided in the composition, according to the guidance provided by Rothbard et al, to provide a composition having desired transport properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 44 and 56, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding independent claim 56, Rothbard et al. furthermore teaches that peptides comprising arginine in addition to other amino acid residues can also be used as the delivery-enhancing polymer, and furthermore teaches that the delivery-enhancing transporters of the invention can be flanked by, or interrupted by, one or even more than one non-guanidino/non-amidino subunits (such as glycine, alanine and cysteine), that do not significantly affect the rate of transmembrane transport of the delivery-enhancing compound compositions (see paragraphs 0048 and 0071, in particular.) Accordingly, Rothbard et al. teaches the polymer having contiguous arginine subunits, with a number of subunits that overlaps with the range claimed in claim 56, the polymer being flanked by one amino acid other than L-arginine, in which the L-arginine subunits would be situated at the C-terminus or the N-terminus of the polymer, as recited in claim 56. Rothbard et al. furthermore teaches providing a dermatologically acceptable carrier in combination with delivery-enhancing polymers, as discussed for claim 44 above, and thus the composition recited in claim 56 is also obvious over the teachings of Rothbard et al.

Regarding claims 45-47 and 57-59, Rothbard et al. teaches providing heptamers of arginine (see paragraph 0048, in particular), which is a polymer containing 7 contiguous arginine subunits, and thus meets the limitation of these claims. Regarding claims 48-50 and 60-62, Rothbard et al. teaches that the delivery-enhancing polymer can be formulated as a lotion for application to skin (see paragraph 0134, in particular.) Regarding claims 51 and 63, Rothbard et al. teaches the subunits are L-arginine (see paragraph 0048, in particular.)

Regarding claims 52-53 and 64-66, Rothbard et al. teaches the topical composition can further comprise skin care actives such as vitamins, antibacterial and analgesics, as well as sunscreen components, among others (see paragraphs 0140-0152, in particular.)

Regarding claims 55 and 67, Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076, in particular.) Rothbard et al. teaches that such compounds can include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076, in particular), and thus are hydrophobic. Rothbard et al. furthermore teaches that the biologically active agent and delivery enhancing transporter are linked by an ionic association, such as between the charged arginine side chain and a charged group on the biologically active agent (see paragraph 0044

and Figure 1, in particular.) While Rothbard et al. does not specifically exemplify linking the biologically active agent to the side chain of the terminal L-arginine subunit, it is considered that one or ordinary skill in the art at the time the invention was made would have found it obvious to provide such an association, based on the ion pair teachings of Rothbard et al, with the expectation of providing a suitable transport pair for skin treatment.

Regarding the methods of therapeutically caring for skin, hair, lips or gums by applying an enhancing effective amount of the composition of claims 44 and 56, as recited in claims 68 and 76, it is noted that Rothbard et al. teaches topical compositions comprising the composition for the treatment of skin (see paragraphs 0138-0152, in particular.) As Rothbard et al. teaches that the composition enhances the transport of biologically active agents, it is considered that Rothbard teaches applying an enhancing effective amount of the composition, as recited in the claims.

Regarding claims 69 and 77, Rothbard et al. teaches applying the composition topically, as discussed above. Regarding claims 71, 79, and 84-85, Rothbard et al. teaches that the composition can comprise retinoids for the treatment of cutaneous aging, and thus teaches alleviating or minimizing the signs of aging of the skin as recited in the claims. Furthermore, regarding the method of minimizing tactile discontinuities as recited in claims 84-85, it is considered that are Rothbard et al. renders obvious the instant method of applying the composition as claimed, the process

of Rothbard et al. must also necessarily minimize tactile discontinuities in the skin, as recited in the claims.

Claims 70 and 78 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 44-69, 71, 76-77, 79 and 84-85 above, and further in view of U.S. Patent No. 4,725,609 to Kull, Jr. et al, issued February 16, 1998.

Rothbard et al. is applied as discussed for claims 44-69, 71, 76-77, 79 and 84-85 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 44 and 56. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the promotion of angiogenesis in hair follicles, as recited in claims 70 and 78.

Kull, Jr. et al. teaches the topical delivery of an agent to promote angiogenesis, re-epithelialization and wound healing (see abstract, in particular.) Kull, Jr. et al. furthermore teaches that the topical formulations can comprise one or more agents to enhance dermal penetration (see column 3, lines 10-35, in particular.) Kull, Jr. et al. demonstrates that application of the topical compositions are capable of epithelial regeneration, including the regeneration of hair follicle epithelium, on wounded skin areas of animals (see column 5, lines 10-28, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the angiogenesis enhancing agent of Kull, Jr. et al. in the delivery-enhancing transporter containing composition of Rothbard et al, and topically delivering to promote angiogenesis in hair follicles, because Rothbard et al. teaches that the delivery-enhancing transporter can be used to enhance the delivery of skin benefit active agents to the skin, and Kull, Jr. et al. teaches that angiogenesis enhancing agents can be topically delivered to the skin to promote angiogenesis and wound healing, including of hair follicles, and can also be suitably provided with dermal penetration enhancing agents. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine and topically apply the angiogenesis enhancing agent of Kull, Jr. et al. with the topical delivery-enhancing

transporter composition of Rothbard et al, with the expectation of providing skin care capable of promoting angiogenesis of epithelium including hair follicle epithelium with enhanced penetration of the angiogenesis active agent.

Claims 72 and 80 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 44-69, 71, 76-77, 79 and 84-85 above, and further in view of U.S. Patent No. 5,785,978 to Porter et al, issued July 28, 1998.

Rothbard et al. is applied as discussed for claims 44-69, 71, 76-77, 79 and 84-85 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 44 and 56. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. also teaches that the active agents can include vitamins (see paragraph 0095, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition to enhance the appearance of lips, as recited in claims 72 and 80.

Porter et al. teaches skin care compositions to improve the appearance of skin, including the area of the upper lip (see abstract, in particular.) Porter et al. teaches that active agents used to improve such areas of the skin include vitamins (see column 1, lines44-54, in particular.) Porter et al. furthermore teaches that such compositions can be administered with a permeation enhancer (see column 4, lines 28-40, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the lip appearance enhancing vitamins of Porter et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to enhance the appearance of lips, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for skin care and can enhance the penetration of vitamins, and Porter et al. teaches that vitamins can be topically applied to improve the appearance of lips and can be applied with a permeation enhancer. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the lip appearance-enhancing vitamins of Porter et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that improves the appearance of lips.

Claims 73 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 44-69, 71, 76-77, 79 and 84-85 above, and further in view of U.S. Patent No. 5,902,593 to Kent et al, issued May 11, 1999.

Rothbard et al. is applied as discussed for claims 44-69, 71, 76-77, 79 and 84-85 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 44 and 56. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition to enhance the sensitivity of skin, as recited in claims 73 and 81.

Kent et al. teaches a topically applied composition comprising an active ingredient, benzalkonium chloride, that increases tissue sensation (see abstract and column 1, lines 25-40, in particular.) Kent et al. teaches that the topical medicament is applied to sensitive tissue areas to produce increased sensitivity to physical contact (see column 1, lines 5-10, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the skin sensitivity enhancing active agent of Kent et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to enhance the sensitivity of skin, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for skin care and to provide skin benefits by enhancing the penetration of active agents, and Kent et al. teaches that active agents can be topically applied to improve the sensitivity of skin. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the skin sensitivity-enhancing agents of Kent et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that improves the sensitivity of skin.

Claims 74 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published

January 24, 2002, as applied to claims 44-69, 71, 76-77, 79 and 84-85 above, and further in view of U.S. Patent No. 5,637,316 to Ribier et al, issued June 10, 1997.

Rothbard et al. is applied as discussed for claims 44-69, 71, 76-77, 79 and 84-85 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 44 and 56. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the stabilization or remodeling of fat, as recited in claims 74 and 82.

Ribier et al. teaches a slimming composition for topical treatment comprising a first dispersion capable of penetration into deep layers of the skin and containing at least one active agent chosen from lipolytic and firming agents (see abstract, in

particular), and thus teaches providing an active agent for the stabilization or remodeling of fat. Ribier et al. teaches that it is desirable to be able to deliver such slimming agents to deep layers of the skin (see column 2, lines 46-54, in particular.) Ribier et al. teaches that active slimming agents for such deep-down action can include caffeine, nicotinic acid derivatives, and gingko biloba, among others (see column 6, line 32, through column 7, line 6, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the slimming active agents of Ribier et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to stabilize or remodel fat, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for therapeutic skin care and can enhance the penetration of active agents, and Ribier et al. teaches that slimming active agents can be topically applied to combat plumpness and firm (see abstract and column 7, lines 45-55, in particular) and are desirably applied with a composition that is capable of delivering the slimming agents to deep layers of the skin. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the slimming active agents of Ribier et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having penetration into deep skin layers that combats plumpness and firms to provide stabilization and remodeling of fat.

Claims 75 and 83 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 44-69, 71, 76-77, 79 and 84-85 above, and further in view of U.S. Patent No. 4,933,172 to Clark, Jr. et al, issued June 12, 1990.

Rothbard et al. is applied as discussed for claims 44-69, 71, 76-77, 79 and 84-85 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 44 and 56. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the treatment of gum regression, as recited in claims 75 and 83.

Clark, Jr. et al. teaches methods for treating destructive periodontal disease comprising applying a therapeutic agent directly to gingival tissue, such as gums (see abstract and column 2, lines 47-62, in particular.) Clark, Jr. et al. teaches that therapeutic active agents are capable of inhibiting the conversion of gingivitis to periodontitis and treating gingivitis (see column 1, lines 5-55, in particular), which are conditions associated with the inflammation of gums and gum recession.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the periodontal disease treating active agent of Clark, Jr. et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to treat gum regression, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied to tissue including skin and mucous membranes to provide benefits to the tissue by enhancing the penetration of active agents, and Clark, Jr. et al. teaches that active agents can be topically applied to gum tissue to treat periodontal disease, and thus treat gum regression. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the periodontal disease treating agents of Clark, Jr. et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that treats periodontal disease.

Response to Arguments

Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.

In particular, Applicants argue that the claims are not obvious in view of Rothbard et al. because Rothbard et al. teaches providing the polyarginine polymer as a delivery enhancing agent in combination with a second treatment agent, and thus does not teach or suggest a composition "consisting essentially of" the vasodilating polymer, as recited in claims 44 and 56. The Examiner respectfully disagrees, and notes that, as discussed above, the transitional phrase "consisting essentially of" as recited in these claims is being interpreted as equivalent to "comprises" for the purposes of searching and applying prior art, as discussed above. The Examiner notes that the instant specification does not indicate what materials are intended to be excluded by such language, and in fact dependent claims 52-54, for example, indicate that a variety of actives are considered to be suitable for, and encompassed by, the composition as claimed. Accordingly, the composition is considered obvious in view of the teachings of Rothbard et al.

Further, with regards to the polymer having subunits with "each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine," as recited in claim 44, the Examiner notes that the

subunits of the polymer of Rothbard do indeed consist of L-arginine, as the non-covalently complexed compounds do not form a part of the "polymer" as taught by Rothbard et al, and instead are a separate bodies that are non-covalently associated with the arginine polymer.

Applicants further argue that Rothbard et al. does not teach that the L-arginine polymers "increase vasodilation," as recited in claims 44 and 56. However, it is noted that as the teachings of Rothbard et al. renders obvious the claimed composition having the L-arginine polymer, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the vasodilation increase, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Furthermore, regarding the "vasodilating amount" of the polymer as recited in the claim, it is noted that Rothbard et al. teaches a broad range of amounts of the polymer that are suitable for treatment compositions, as discussed above, and thus it is considered that one of ordinary skill in the art would have found it obvious to optimize

and/or vary the amount of the polymer provided in the composition, such as an amount that also happens to be a vasodilating amount.

Also, it is noted that the vasodilating properties of polyarginine polymers are well known in the art. See for example the article entitled "Basic Polyamino Acids Rich in Arginine, Lysine, or Ornithine Cause both Enhancement of and Refractoriness to Formation of Endothelium-Derived Nitric Oxide in Pulmonary Artery and Vein" by Ignarro et al, 1989, Circulation Research, Vol. 64, pages 315-329.

Applicants also argue that Rothbard et al. teaches away from using the arginine oligomers taught therein for vasodilation, because Rothbard exemplifies a non-covalent oligomer/taxol complex, which is a drug widely used for the treatment of cancers. Applicants argue that one of ordinary skill in the art would not be motivated to provide vasodilation in such a cancer-treatment embodiment because an increase in blood flow resulting from vasodilation could promote tumor growth. The Examiner disagrees with Applicants interpretation of this example as teaching away from the instant invention. The Examiner notes that Rothbard et al. does not teach that vasodilation is undesirable, or that ingredients that cause vasodilation should be avoided. While Rothbard et al. does provide an example of an oligomer/taxol complex, Rothbard et al. also teaches that numerous other different active agents such as antibacterial agents, antiviral agents, analgesic agents, etc, can also be incorporated into the composition, and exhibit beneficial effects in combination with the delivery enhancing oligomer (see

paragraphs 0094-0104, in particular.) Thus, in view of Rothbard et al's teachings *in their entirety* it is considered that one of ordinary skill in the art would not have been taught away from using vasodilating polymers of Rothbard et al, or providing the polymers in methods in which vasodilation may be desired. Furthermore, as discussed above, as Rothbard et al. teaches and/or renders obvious the polymers as claimed, it is considered that the polymers must necessarily also have the vasodilating property as claimed as products and their properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, the article entitled "Basic Polyamino Acids Rich in Arginine, Lysine, or Ornithine Cause both Enhancement of and Refractoriness to Formation of Endothelium-Derived Nitric Oxide in Pulmonary Artery and Vein" by Ignarro et al, 1989, Circulation Research, Vol. 64, pages 315-329, teaches that the vasodilating properties of polyarginine polymers are well known in the art. U.S. Patent No. 5,571,794 teaches providing vasodilators in topical compositions for cosmetic lip augmentation; U.S. Patent No. 5,480,889 teaches providing vasodilators for the treatment of baldness; G.B. 2002233 teaches providing vasodilators for cosmetic

slimming; U.S. Patent No. 5,665,731 teaches providing vasodilators for the treatment of gums; U.S. Patent Nos. 6,403,658 and 6,031,002 teach the treatment of sexual dysfunction with vasodilators; and WO 01/78730 and WO 97/25023 teach skin treatments, including treatment of wrinkled and aging skin, with vasodilators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SAVEENI PADMANABHAN
SUPERVISORY PATENT EXAMINER